

### REMARKS

Claims 1, 3, 4, 6-7, 9, 12-13, 16-18, 21-24, 27-29, 31, 55, and 57-62 are pending, with claims 1, 4, 22, 55, and 62 being independent. Claims 1, 4, 22, and 55 have been amended. Support for the amendments can be found in the originally-filed specification, at least in Figs. 1-10 and paragraphs 26-30. No new matter has been introduced. Claim 62 is new and derives support at least from the above-mentioned figures and paragraphs.

#### Claim Rejections

Claims 1, 3, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, 55, and 57-61 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner argues that the limitations, “the tip is immovable relative to the handle and the shaft” in claims 1 and 55 and “the device does not allow for independent positioning of the needle when the needle is attached to the shaft” in claim 22 are not supported in the specification. These claims have been amended to delete these limitations. Therefore, these claims are in condition for allowance and, since claims 3, 6, 7, 9, 12, 13, 16-18, 21-24, 27-29, 31, and 57-61 depend either directly or indirectly from claims 1 and 55, it is respectfully requested that the rejection be withdrawn.

Claims 21-24, 27-29, 31, and 58-60 have been rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner argues that it is not certain how the tip of claim 22 is selectively detachable from the shaft when the tip is said to be immovable relative to the handle and the shaft. Also, the Examiner argues that it is not certain how the device does not allow for independent positioning of the needle when the needle is attached to the shaft when the needle is said to be detachable from the shaft. Claim 22 has been amended to delete the limitation that the device does not allow for independent positioning of the needle when the needle is attached to the shaft. Therefore, claim 22 is in condition for allowance and, since claims 23-24, 27-29, 31, and 58-60 depend either directly or indirectly from claim 22, it is respectfully requested that the rejection be withdrawn.

Claims 1, 3, 6, 7, 9, 12, 13, 16-18, 55, 57, and 61 have been rejected as being unpatentable under 35 USC 103 over Mollenauer in view of Beyer et al and further in view of Zocher. Applicant requests withdrawal of this rejection for the following reasons.

Independent claim 1 recites a suturing device including a handle extending along an axial direction, an elongated shaft separately attached to a distal end of the handle, and a sharpened tip separately attached to a distal end of the elongated shaft. The sharpened tip includes an exposed, tapered, and closed opening that is continuously tapered along a length of the opening from a distal closed edge to a proximal closed edge and configured to trap a suture at a selected point within the opening and permit the suture to pass lengthwise through the opening.

Independent claim 55 recites a suturing device including a handle extending along an axial direction, an elongated shaft separately attached to a distal end of the handle, a sharpened tip separately attached a distal end of the elongated shaft, and a suture coupled with the sharpened tip. The sharpened tip has a piercing portion configured to pierce tissue during a suturing procedure and has an exposed, tapered, and closed opening, where the opening is continuously tapered along a length of the opening from a distal closed edge to a proximal closed edge. The suture has a suture portion extending outward from the sharpened tip to permit the suture to be grasped and manipulated relative to the sharpened tip, the suture portion disposed to be carried by the sharpened tip through tissue which has been pierced by the piercing portion. The opening is configured to permit the suture to pass lengthwise through the opening.

Neither Mollenauer, Beyer, Zocher nor any proper combination of the three describes or suggests a handle, a shaft separately attached to the handle, and a sharpened tip separately attached to the shaft, as recited in claims 1 and 55. The closest prior art is Mollenauer, which shows in figure 12 a device similar to Applicants, albeit with only a handle and a coiled projection attached to the handle. The coiled projection has a pointed distal end. The Examiner equates the coiled projection with the pointed distal end to the elongated shaft and the sharpened tip of Applicants' device. The pointed distal end of the coiled projection is integral to the coiled projection, rather than being separately attached as in Applicants' device. The Mollenauer device of Fig. 12 does not include a handle, a shaft separately attached to the handle, and a sharpened tip separately attached to the shaft.

Accordingly, for at least these reasons, claims 1 and 55 are allowable over Mollenauer. Claims 3, 6, 7, 9, 12, 13, 16-18, 57, and 61 depend from claims 1 and 55, and are allowable for at

least the reasons that claims 1 and 55 are allowable and for containing allowable subject matter in their own right.

Claim 4 has been rejected as being unpatentable over Mollenauer in view of Orthwine et al and further in view of Leighton. Applicant requests withdrawal of this rejection for the following reasons.

Claim 4 recites a suturing device including a handle extending along an axial direction, an elongated shaft separately attached to a distal end of the handle, and a sharpened tip separately attached to a distal end of the elongated shaft. The sharpened tip includes an exposed and closed opening that includes an open central axial region in which the central axial region is narrower than proximal and distal edge regions along a direction perpendicular to the axial direction to trap a suture at a selected point within the opening and to permit the suture to pass lengthwise through the opening.

Applicant requests withdrawal of the rejection of claim 4 because neither Mollenauer, Orthwine, Leighton, nor any proper combination of the three describes or suggests a suturing device including a handle, an elongated shaft separately attached to a distal end of the handle, and a sharpened tip separately attached to a distal end of the shaft. As stated above, Mollenauer's device includes a handle and a coiled projection. The coiled projection has a sharp distal end. The device does not have a handle, a shaft separately attached to the handle, **and** a sharpened tip separately attached to the shaft

Claims 21-24, 27-29, 31, and 58-60 have been rejected as being unpatentable over Mollenauer in view of Beyer and Zocher and further in view of Yoon. Applicant requests withdrawal of this rejection for the following reasons.

Claim 21 depends from claim 1, which was rejected as being unpatentable over Mollenauer in view of Zocher and Beyer. As discussed above, neither Mollenauer, Beyer, Zocher nor any proper combination of the two describes or suggests a handle, a shaft separately attached to the handle, and a sharpened tip separately attached to a distal end of the shaft, as recited in claim 1. Yoon does not remedy the failure of Mollenauer, Beyer, and Zocher to describe or suggest this subject matter.

Accordingly, claim 1 is allowable over any proper combination of Mollenauer, Beyer, and Yoon, and claim 21 is allowable for at least the reasons that claim 1 is allowable.

Independent claim 22 recites a suturing device including a handle extending along an axial direction, an elongated shaft separately attached to a distal end of the handle at a proximal end of the shaft, and a detachable needle at a distal end of the shaft. The needle has a side closed through hole into which a suture is attached and the closed through hole is continuously tapered along a length of the through hole from a distal closed edge to a proximal closed edge. Applicant requests withdrawal of this rejection because neither Mollenauer, Beyer, Zocher, Yoon, nor any proper combination of the four describes or suggests this independent positioning limitation, as recited in amended independent claim 22.


Accordingly, claim 22 is allowable over any proper combination of Mollenauer, Beyer, Zocher, and Yoon. Claims 23, 24, 27-29, 31, and 58-60 depend from claim 22, and are allowable for at least the reason that claim 22 is allowable and for containing allowable subject matter in their own right.

Applicant does not acquiesce to the characterizations of the art. For brevity and to advance prosecution, however, Applicant may have not addressed all characterizations of the art, but reserve the right to do so in further prosecution of this or a subsequent application.

The absence of an explicit response by the Applicant to any of the Examiner positions does not constitute a concession of the Examiner's positions. The fact that Applicant's comments have focused on particular arguments does not constitute a concession that there are not other good arguments for patentability of the claims. All of the dependent claims are patentable for at least the reasons given with respect to the claims on which they depend. Please apply any charges or credits to Deposit Account No. 192563.

Respectfully submitted,

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